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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,998	12/16/2005	Richard B. Williams	PRONOV.001BNP	9584

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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07/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/560,998	Applicant(s) WILLIAMS, RICHARD B.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-36, 38 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12, 14-36 and 38 are pending in the case.

Receipt of the Information Disclosure Statement on 12/16/05 is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-12, in the reply filed on 5/2/08 is acknowledged.

Claims 14-26 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/08.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/529,331, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application 60/529,331 does not disclose mRNA modified by a crosslinker which is 2-thiocytosine, 2-

thioridine, 4-thiouridine, 5-iodocytosine, 5-iodouridine, 5-bromouridine, 2-chloroadenosine, arylazides, and modifications or analogues thereof (i.e. claim 5 and 11).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Teare et al. (Nucleic Acids Research 18, 4:855-864, 1990).

Teare et al. disclose a modified mRNA molecule operable to crosslink to a tRNA molecule, wherein the modified mRNA molecule comprises a crosslinker located on or near a stop codon, and wherein the crosslinker is psoralen (see Fig. 2, SSP-410). The crosslinker can be activated to form one or more covalent bonds with the tRNA, using light. The crosslinker is a modified base that is incorporated directly into the mRNA (see Fig. 1). In addition, since the specification has defined a pseudo stop codon to include any codon whose corresponding tRNA molecule has been depleted in a system of in vitro translation, any codon could be considered a “pseudo stop codon”, and therefore, the codons which have psoralen molecules in the reference could each be defined as a pseudo stop codon under appropriate conditions.

Claims 1-4, 6-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yabusaki et al. (US Patent 4,599,303).

Yabusaki et al. disclose a modified mRNA molecule operable to crosslink to a tRNA molecule, wherein the modified molecule comprises a crosslinker which may be psoralen, which may be on or near a stop codon or pseudo stop codon, since the reference discloses incorporated said psoralen at maximal positions in the molecule (see col. 3, lines 35-50; col. 11, lines 25-35). Furthermore, since the specification has defined a pseudo stop codon to include any codon whose corresponding tRNA molecule has been depleted in a system of in vitro translation, any codon could be considered a "pseudo stop codon", and therefore, the codons which have psoralen molecules in the reference could each be defined as a pseudo stop codon under appropriate conditions.

Claims 1-5, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Favre et al. (J. Photochem. And Photobiol., 42 (1998), 109-124) (cited by applicants).

Favre et al. disclose a modified mRNA operable to crosslink to a tRNA molecule, wherein the modified molecule comprises a crosslinker which may be 4-thiouridine, at or near a stop codon (see paragraph bridging pages 116 and 117). The reference discloses that other thionucleotides such as 4-thiothymine, 6-thioguanin and any other thionucleosides may be incorporated directly into RNA and photoactivated with light to crosslink RNA (see abstract).

Claims 1-5, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (J. Biol. Chem. 269, 52, 33164-33170, 1994).

Brown et al. disclose a mRNA comprising a modified mRNA operable to crosslink to a tRNA molecule wherein the modification is 4-thiouridine incorporated at the stop codon or near a pseudostop codon (see abstract).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, claims 5 and 11 are directed to modified mRNA molecules having a crosslinker which may be any modification or analogue of the molecules listed in the claims, i.e. 2-thiocytosine, 2-

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thioridine, 4-thiouridine, 5-iodocytosine, 5-iodouridine, 5-bromouridine, 2-chloroadenosine, and arylazides. While the specification has adequate written description of the above listed molecules to be used as crosslinkers in mRNA, there is no disclosure of the structural limitations of the genus represented by modifications or analogues of said molecules nor any guidance for the production of said modifications or analogues.

There is no description of the identifying characteristics for recognizing that a derivative or analogue may be incorporated into an mRNA and be operable to crosslink to a tRNA. One skilled in the art would conclude that the disclosure of particular molecules which may be incorporated into mRNA and which may be operable to crosslink to a tRNA molecule, is not representative of the undefined genus of derivatives and analogues recited in the claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Therefore, the inventor, at the time the application was filed was not in possession of the broad genus comprising derivatives and analogues of 2-thiocytosine, 2-thioridine, 4-thiouridine, 5-iodocytosine, 5-iodouridine, 5-bromouridine, 2-chloroadenosine, arylazides, needed to practice the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
7/17/08